

IN THE UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF ILLINOIS

JOHN MARK DEVOUS)	
)	
Plaintiff,)	
)	
vs.)	Case No.:
)	
MEDTRONIC USA, INC.,)	
MEDTRONIC, INC., MEDTRONIC)	
MINI MED, INC., MINI MED)	
DISTRIBUTION, INC.)	
)	
Defendants.)	

COMPLAINT

NOW COMES the Plaintiff, John DeVous, by and through his attorneys,
Howerton, Dorris, Stone & Lambert, and for his Complaint, states:

JURISDICTION

1. John DeVous is an adult citizen of the state of Illinois living at all times relevant in Equality, Illinois.

2. Defendant Medtronic, Inc. is a foreign corporation organized and existing under the laws of Minnesota with its principal place of business at 710 Medtronic Parkway, Minneapolis, MN 55432.

3. Defendant Medtronic USA, Inc. is a foreign corporation organized and existing under the laws of Minnesota with its principal place of business at 710 Medtronic Parkway, Minneapolis, MN 55432.

4. Defendant Medtronic Mini Med, Inc. is a foreign corporation organized and existing under the laws of Delaware with its principal place of business at 18000 Devonshire Street, Northridge, CA 91325.

5. Defendant Mini Med Distribution, Inc. is a foreign corporation organized and existing under the laws of Delaware with its principal place of business at 18000 Devonshire Street, Northridge, CA 91325.

6. This Court has diversity jurisdiction pursuant to 28 U.S.C. §1332 because the amount in controversy exceeds \$75,000.00 exclusive of interest and costs and this case is between citizens of different states.

7. Venue is proper in this Court pursuant to 28 U.S.C. §1391.

FACTS

1. John DeVous was injured as a result of a defective Medtronics product, which occurred in his home in Equality, Illinois on August 30, 2017.

2. On and prior to August 30, 2017 John DeVous used a Medtronic Mini Med model 630G insulin pump to deliver insulin into his bloodstream to treat his diabetes.

3. The model 630G Medtronic Mini Med Insulin Pump works in conjunction with Medtronic Mini Med Quick Set Paradigm infusion components, which when coupled with the pump, delivers insulin into its intended users.

4. The Defendants designed, manufactured, marketed and distributed the 630G pump and the Mini Med Quick Set Paradigm infusion components to deliver insulin from an insulin pump to a diabetes patient in a measured and safe amount.

5. The Mini Med Quick Set Paradigm infusion components consist of a membrane through which insulin passes from the pump reservoir into

disposable plastic tubes which then transport the insulin into the patient's body in a measured and safe amount.

6. Prior to August 30, 2017, Defendants became aware of problems with certain lots of the Medtronic Mini Med Quick Set Paradigm infusion components, the problem being the over delivery of insulin.

7. Prior to August 30, 2017, John DeVous received shipments of the defective Medtronic Mini Med Quick Set Paradigm infusion components from Defendants.

8. On August 30, 2017, at his home in Equality, Illinois, John DeVous changed out the infusion components he had been using with the defective Medtronic Mini Med Quick Set Paradigm infusion components.

9. Following the change to the defective Medtronic Mini Med Quick Set Paradigm infusion components, the pump, in combination with the defective Mini Med Quick Set Paradigm infusion components, delivered an overdose of insulin into John DeVous's body.

10. The overdose of insulin caused John DeVous to suffer severe hypoglycemia.

11. The severe hypoglycemia caused John DeVous to have a seizure.

12. The seizure resulted in physical harm, including a dislocation of his shoulder and fracture of his arm.

13. The membrane of Medtronic Mini Med Paradigm infusion component that John DeVous was using on August 30, 2017 failed to work as

designed, in that it permitted insulin to be over delivered from the pump's reservoir through the membrane and into his body.

14. Prior to August 30, 2017, John DeVous did not know that Mini Med Quick Set Paradigm infusion components shipped to him for use with his Medtronic 630G insulin pump were defective such that when used in conformance with the Defendant's instructions he was at risk of over delivery of insulin which could lead to a hypoglycemic episode and injury.

15. On September 7, 2017 Medtronic issued an urgent medical device recall regarding Medtronic Mini Med Infusion Sets.

16. The Medtronic Mini Med Paradigm infusion components at issue were subsequently recalled by Defendants on September 7, 2017 due to the defective membrane condition described herein.

17. The recall notice states that "Medtronic has become aware of recent reports of potential over delivery of insulin shortly after an infusion set change." Medtronic's recall further notes it has received reports of hypoglycemia requiring medical attention related to this issue, which Medtronic can see it is going to result in "hypoglycemia, and in extreme cases, death."

18. The recall notice states that this problem is caused by fluid blocking the infusion set membrane during the priming/fill tubing process which prevents the infusion set from working properly. The result can be fast delivery of overdoses of insulin.

19. The recall notice also announces that Medtronic had an alternative infusion set design which contains a “new and enhanced membrane material that significantly reduces the risk.”

20. Over delivery of insulin is a serious health risk and poses an unreasonable risk of harm to its users.

21. The over delivery of insulin into John DeVous occurred because of the defect and circumstances described by Medtronic in its recall materials.

COUNT I

22. At all times relevant to the Complaint, the Defendants were in the business of designing, manufacturing, marketing, testing, labeling, selling and/or distributing Medtronic Mini Med Paradigm infusion components.

23. The Medtronic Mini Med Paradigm infusion components shipped to John DeVous were defective and unreasonably dangerous at the time they left Defendants control.

24. The defective and unreasonably dangerous conditions existed when Defendants sold the product.

25. The defective and unreasonably dangerous conditions existed when John DeVous received the product.

26. As a direct and proximate result of the unreasonably dangerous condition of the Medtronic Mini Med Paradigm infusion components, John

DeVous was injured, experienced pain, suffering, disability, disfigurement, loss of income, loss of a normal life and medical expense.

WHEREFORE, John DeVous prays for Judgment against Defendants, plus cost of suit.

HOWERTON, DORRIS, STONE & LAMBERT

By: _____


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COUNT II

Negligence and Willful and Wanton Misconduct

27. Prior to August 30, 2017, Defendants knew their Medtronic Mini Med Paradigm infusion components were unreasonably dangerous and defective when used as designed and directed because of the membrane defects described herein and in Medtronic's recall materials.

28. Prior to August 30, 2017, Defendants had a duty to exercise reasonable care to warn, issue recalls, and/or otherwise act with dispatch to protect its customers from the life-threatening defect described herein.

29. Defendants breached their duties, in that they:

- a. failed to timely inform users including John DeVous of the defect;
- b. failed to timely implement and execute corrective and preventative actions to eliminate injuries;

- c. continued to promote and market the product despite knowledge that its defective components could cause serious injury and even death;
- d. acted with conscious indifference and utter disregard to the harm its defect might cause.

30. As a direct and proximate result of these negligent and willful and wanton acts, John DeVous was injured, experienced pain, suffering, disability, disfigurement, loss of income, loss of a normal life and medical expense.

WHEREFORE, John DeVous prays for Judgment against defendants, compensatory and punitive damages, plus cost of suit.

HOWERTON, DORRIS, STONE & LAMBERT

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